

Remarks

By this amendment, Applicants have canceled claims 1-21 without prejudice or disclaimer, and added new claims 22-47. Applicants reserve the right to pursue the canceled claims in a continuation or divisional application(s).

Claims 22-47 are supported at least by original claims 1-19 and pages 17-26 of the specification. In particular, claims 22-27 are supported at least by original claims 1-12 and the specification from page 17, line 14, to page 18, line 15. Claim 28 is supported at least by page 20, lines 3-9, of the specification. Claim 29 is supported at least by page 26, lines 11-16, of the specification. Claims 30-31 are supported at least by original claims 4-5. Claim 32 is supported at least by the specification from page 21, line 21, to page 22, line 11. Claim 33 is supported at least by the specification from page 23, line 26, to page 24, line 20. Claims 34-35 are supported at least by the specification from page 22, line 15, to page 23, line 5. Claim 36 is supported at least by page 23, lines 9-19, of the specification. Claim 37 is supported at least by the specification from page 24, line 24, to page 25, line 15. Claim 38 is supported at least by the specification from 25, line 19, to page 26, line 4. Claims 39 and 40 are supported at least by page 19, lines 11-15, of the specification. Claim 41 is supported at least by original claim 15-16 and 18-19. Claim 42 is supported at least by page 22, lines 12-14, of the specification. Claim 43 is supported at least by page 25, lines 16-18, of the specification. Claim 44 is supported at least by page 23, lines 6-8, of the specification. Claim 45 is supported at least by page 23, lines 20-25, of the specification. Claim 46 is supported at least by page 25, lines 16-18, of the specification. Claim 47 is supported at least by page 26, lines 5-10, of the specification.

Applicants respectfully submit that the addition of the new claims does not introduce new matter. Accordingly, entry of these claims is respectfully requested.

Objection to Claim 16

On page 2, the Office Action objects to claim 16 for a spelling error. Applicants have canceled claim 16, thereby rendering the objection moot. Withdrawal of the objection is, therefore, respectfully requested.

Rejection Under 35 U.S.C. §103(a)

On pages 2-4, Applicants reject claims 1, 3-11, and 14-21 under 35 U.S.C. §103(a) as being obvious over Sham (WO 97/21685) in view of Yamamoto I (U.S. Patent No. 5,264,223) or Yamamoto II (U.S. Patent No. 5,756,123). Applicants have canceled these claims without prejudice or disclaimer, thereby rendering the rejection of these claims moot. Accordingly, withdrawal of the rejection of these claims is respectfully requested.

In addition, Applicants respectfully submit that claims 22-47 are not obvious over Sham in view of Yamamoto I or Yamamoto II. Claims 23-47 depend from claim 22, which recites a solution comprising “(a) (2S,3S,5S)-5-(N-(N-((N-methyl-N-((2-isopropyl-4-thiazolyl)-methyl)amino)carbonyl)-L-valinyl)amino-2-(N-((5-thiazolyl)methoxy-carbonyl)-amino)-1,6-diphenyl-3-hydroxyhexane (ritonavir) or a combination of ritonavir and another HIV protease inhibiting compound, or pharmaceutically acceptable salts thereof, in an amount of from 1% to 50% by weight of said solution; (b) a pharmaceutically acceptable medium and/or long chain fatty acid, or a mixture of pharmaceutically acceptable medium and/or long chain fatty acids, in an amount of from 30% to 75% by weight of said solution; (c) ethanol or propylene glycol in an amount of from 1% to 15% by weight of said solution; (d) water in an amount of from 0.4% to 3.5% by weight of said solution; and, optionally, (e) a pharmaceutically acceptable surfactant.”

Applicants respectfully submit that Sham and Yamamoto I/II, either alone or in combination, does not teach or suggest a solution having each and every component of claim 22. For instance, Yamamoto I and II are related to hard capsules, not solutions. Accordingly, Applicants respectfully submit that Sham and Yamamoto I/II do not render claim 22 obvious. *See MPEP 2143.03 (“To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art”).*

Because claims 23-47 depend from claim 22, Applicants respectfully submit that claims 23-47 are also patentable over Sham in view of Yamamoto I or II.

Rejection Under 35 U.S.C. §103(a)

On pages 4-5, Applicants reject claims 1, 3-11, and 14-21 under 35 U.S.C. §103(a) as being obvious over Al Razzak (U.S. Patent No. 5,948,436). As noted above, Applicants have canceled claims 1, 3-11, and 14-21 without prejudice or disclaimer, thereby rendering the

rejection of these claims moot. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection of these claims.

In addition, Applicants respectfully submit that claims 22-47 are not obvious over Al Razzak. Specifically, Applicants submit that Al Razzak does not teach or suggest the use of “a pharmaceutically acceptable medium and/or long chain fatty acid, or a mixture of pharmaceutically acceptable medium and/or long chain fatty acids, in an amount of from 30% to 75% by weight of said solution,” as recited in claim 22. Therefore, Al Razzak does not teach each and every element of claim 22. Accordingly, Applicants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness. See MPEP 2143.03 (“To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art”).

Because claims 23-47 depend from patentable claim 22, Applicants respectfully submit that these claims are also patentable over Al Razzak.

On pages 4-5, the Office Action contends that Al Razzak, at column 6, line 50, discloses a composition containing fatty acids, and that the term “fatty acid” as used in the present claims encompasses fatty acid ester. Applicants respectfully traverse.

MPEP 2111.01 mandates that the words of a claim be given their “plain meaning” unless they are defined in the specification. MPEP 2111.01 also mandates that plain meaning be the ordinary and customary meaning given to the term by those of ordinary skill in that art. In addition, MPEP 2111.01 states that the ordinary and customary meaning of a term may be evidenced by a variety of sources, including the claims themselves, dictionaries, treatises, the written description, the drawings, and the prosecution history.

Applicants respectfully submit that the ordinary and customary meaning of the term “fatty acid,” as understood by those of ordinary skill in that art, does NOT include fatty acid ester. The present claims do not recite “fatty acid ester.” The specification of the present application does not define “fatty acid” to encompass fatty acid ester. In fact, Examples 8-9 of the present application explicitly describes the use of “Oleic Acid, NF.” As appreciated by those of ordinary skill in the art, “NF” refers to the National Formulary standard that defines the strength, quality, and purity of the name compound. One of ordinary skill in the art would not consider “Oleic Acid, NF” an oleic acid ester.

Moreover, Stedman's Medical Dictionary (25th Edition, Williams & Wilkins, 1990) defines "fatty acid" as "[a]ny acid derived from fats by hydrolysis (e.g., oleic, palmitic, or stearic acids); any long-chain monobasic organic acid." See Exhibit 1. Stedman's Medical Dictionary does not suggest that "fatty acid" can be construed to also refer to fatty acid ester.

The Office Action contends that Al Razzak, at column 6, line 50+, teaches a composition containing fatty acid. However, at column 6, line 50+, Al Razzak merely shows that when Gelucire is characterized (e.g., by hydrolysis), the fatty acid moieties in the glyceride include certain amounts of caprylic acid, capric acid, lauric acid, myristic acid, palmitic acid, and stearic acid. Al Razzak, at column 6, line 50+, does not suggest that Gelucire includes fatty acids as individual components of a composition. A contrary construction would also include KOH as an individual component of Gelucire, which is inconsistent with the ordinary and customary meaning of the term "Gelucire."

The Office Action also contends that the issue of whether fatty acid encompasses fatty acid ester "is primarily one of semantic laxity." However, all of the examples cited by the Office Action refer to moieties in a molecule, as opposed to individual components of a composition. For instance, even assuming that the term "amino acid" may be used to refer to a residue in a polypeptide, one of ordinary skill in the art would not consider that a claim to a pharmaceutical composition comprising 1% water, 2% ethanol and 3% of tyrosine would literally encompass a composition where tyrosine is provided only as a residue of a polypeptide.

In addition, Applicants respectfully submit that even if any semantic laxity exists for the term "fatty acid," such semantic laxity does not represent the plain meaning of the term as understood by those of ordinary skill in the art. Applicants hereby respectfully request the Examiner to produce documentary proof to support the proposition that the plain meaning of the term "fatty acid" includes fatty acid ester.

The Office Action further contests that "[i]f it were really the case that applicants believed that the term 'fatty acid' invariably means *free fatty acid*, applicants would feel no reluctance in amending the claims to recite the latter term." However, Applicants respectfully submit that the term "fatty acid" as used herein should not be limited to "free" fatty acid. This is because a fatty acid molecule can interact with other molecules in a solution and therefore may not be "free."

Based on all of the above reasons, Applicants respectfully submit that the ordinary and customary meaning of the term “fatty acid” does not encompass fatty acid ester. Because Al Razzak does not teach or suggest the use of 30-75% of fatty acid(s), Applicants respectfully submit that Al Razzak does not render claims 22-47 obvious.

Applicants also wish to direct the Examiner’s attention to MPEP 2111.01, which states that “[w]hile the claims of issued patents are interpreted in light of the specification, prosecution history, prior art and other claims, this is not the mode of claim interpretation to be applied during examination.” Therefore, Applicants respectfully submit that the construction of the term “fatty acid” as not encompassing fatty acid ester for the purpose of examination should not by itself preclude the inclusion of fatty acid ester as an equivalent of fatty acid under the doctrine of equivalents.

Numerical Ranges

Applicants respectfully submit that the numerical ranges recited in claims 22-47 are definite under 35 U.S.C. §112, second paragraph. As indicated in MPEP 2173.05(c), the court has held that a composition claimed to have a theoretical content greater than 100% (i.e., 20-80% of A, 20-80% of B and 1-25% of C) is not indefinite simply because the claims may be read in theory to include compositions that are impossible in fact to formulate. *See In re Kroekel*, 504 F.2d 1143, 183 USPQ 610 (CCPA 1974). Accordingly, Applicants respectfully submit that the numeric ranges in claims 22-47 are definite.

Conclusion

For at least the reasons set forth above, Applicants respectfully submit that this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly solicited. Although Applicants believe that the fees paid herewith are correct, the Commissioner is hereby authorized to charge any payment deficiency to deposit account number 01-0025 referring to docket number 6499.US.O2.

Should the Examiner believe that anything further is desired in order to place the application in even better condition for allowance, the Examiner is invited to contact Applicants' representative designated below.

Respectfully submitted,



Xu Zhang
Lim. Rec. No. L0116

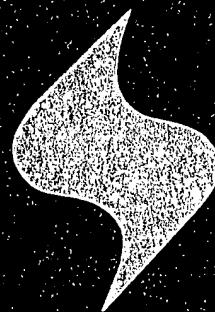
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Stedman's

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25th Edition
ILLUSTRATED



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Printed in the United States of America

English Language Co-editions
Asian 1967, 1972, 1976
Indian 1967, 1973
Taiwan 1972, 1978

Translated Editions
Greek 1976
Indian 1977
Japanese 1977, 1985
Portuguese 1976
Spanish (in press)

Library of Congress Cataloging-in-Publication Data

Stedman, Thomas Lathrop, 1853-1938.
[Medical dictionary]
Stedman's medical dictionary.—25th ed.
p. cm.
ISBN 0-683-07916-6
1. Medicine—Dictionaries. I. Title. II. Title: Medical dictionary
[DNLM: 1. Dictionaries, Medical. W 13 S812m]
R121.S8 1989
610'.3—dc20
DNLM/DLC
for Library of Congress

89-16579
CIP

90 91 92 93 94
2 3 4 5 6 7 8 9 10

found in herbivores, especially in Africa.

Fascioliasis, the liver or sheep liver fluke, the common liver fluke inhabiting the bile ducts of sheep and cattle; the intermediate hosts are aquatic snails, *Lymnaea* or related genera; after the cercariae escape, they become encysted on watercress, lettuce, and other waterplants by which they gain access to the intestinal canal; rarely, this fluke is reported from humans, in whom it may cause considerable biliary damage.

fasciola, pl. **fasciolas** (fa-sé'ō-lä, fa-sí'ō-lä; -ō-lë) [L. dim. of *fascia*, band; *fillet*]. A small band or group of fibers.

fascicular (fa-sé'ō-lär, fa-sír). Relating to the gyrus fasciolaris.

fasciolosis (fas'é-ō-lí'ā-sis, fa-sí'ō-lí'ā-sis). Infection with a species of *Fasciola*.

fasciolid (fa-sé'ō-lid, fa-sír). A member of the family *Fasciolidae*.

Fascioloides magna (fas'é-ō-loy'dēz mag'nă, fa-sí'ō-). A species of fasciolid flukes found in the lungs and liver of deer and sometimes cattle in North America; it is not known to infect man.

fasciolopsis (fas'é-ō-lop'sis, fa-sí'ō). Parasitization by any of the flukes of the genus *Fasciolopsis*.

Fasciolopsis (fas'é-ō-lop'sis, fa-sí'ō) [*Fasciola* + G. *opsis*, form, appearance]. A genus of very large intestinal fasciolid flukes.

buski, the large intestinal fluke, a species found in the intestine of humans in eastern and southern Asia; transmitted via ingestion of water chestnuts or other vegetation contaminated with infective metacercariae.

Fathoni, a species reported from China in a few cases in the intestine or liver; possibly the same as *F. buski*.

fascioplasty (fash'é-ō-plas-tē). Plastic surgery of a fascia.

fascorrhaphy (fash-e-ō'rā-fē) [fascio- + G. *raphē*, suture]. Aponeurorhaphy; suture of a fascia or aponeurosis.

fascotomy (fash-e-ōt'ō-mē) [fascio- + G. *tomē*, incision]. Incision through a fascia; used in the treatment of certain vascular disorders and injuries when marked swelling is anticipated which could compromise blood flow; f. is often combined with embolectomy in the treatment of acute arterial embolism.

fascitis (fa-sí'tis). Fasciitis.

fast [A.S. *feast*, firm, fixed]. Durable; resistant to change; applied to stained microorganisms which cannot be decolorized. See also *acid-fast*.

fast green FCF [C.I. 42053]. An acid arylmethane dye widely used in histology and cytology and less subject to fading than light green FCF which it has replaced in many procedures; used as a quantitative cytochemical stain for histones at alkaline pH after extraction of DNA, and also in electrophoresis as a protein stain.

fastidious (fas-tid'ē-üs). In bacteriology, having complex nutritional requirements.

fastidium cibi (fas-tid'ē-üm kib'i) [L.]. Rarely used term for fickle or finicky appetite, caused by distaste for food.

fastigium (fas-ti-gā'tüm) [L. *fastigatus*, pointed]. *Nucleus fastigii*.

fastigium (fas-tij'ē-üm) [L. top, as of a gable; a pointed extremity].

1. Apex of the roof of the fourth ventricle of the brain, an angle formed by the anterior and posterior medullary vela extending into the substance of the vermis. 2. The acme or period of full development of a disease.

fastness (fast'nes). The state of tolerance exhibited by bacteria to a drug or other agent. See *fast*.

fat [A.S. *feaf*]. 1. Adipose tissue. 2. Obese; corpulent. 3. A greasy, soft-solid material, found in animal tissues and many plants, composed of a mixture of glycerol esters; together with oils they comprise the homolipids.

fat [L. *hibernare*], hibernating or interscapular gland; interscapular hiber-

noma; multilocular f. or adipose tissue; thermogenic tissue that is composed of cells containing numerous small fat droplets; lobular masses are found in the interscapular and mediastinal regions and other locations; although found most frequently in certain hibernating animals, it is also found in pigs, rodents, and the newborn of man.

caul f., the f. contained in the caul.

multilocular f., brown f.

neutral f., a triester of fatty acids and glycerol.

saturated f., see saturated fatty acid.

split f., free fatty acids, as reduced by the action of lipases, neutral fats, or phospholipids.

unilocular f., white fat (2); adipose tissue in which the fat is present in a single droplet within the fat cells.

unsaturated f., see unsaturated fatty acid.

white f., (1) adipose tissue; (2) unilocular f.

fatal (fā-täl') [L. *fatalis*, of or belonging to fate]. Pertaining to or causing death; denoting especially inevitability or inescapability of death.

fatality (fā-täl'i-tē). 1. A condition, disease, or disaster ending in death. 2. An individual instance of death.

fatigability (fat'i-gă-bil'i-tē). A condition in which fatigue is easily induced.

fatigable (fat'i-gă-bl) [L. *fatigabilis*, easily tired, fr. *fatigo*, to tire]. Tiring on very slight exertion.

fatigue (fā-tēg') [Fr., fr. L. *fatigo*, to tire]. 1. That state, following a period of mental or bodily activity, characterized by a lessened capacity for work and reduced efficiency of accomplishment, usually accompanied by a feeling of weariness, sleepiness, or irritability; may also supervene when, from any cause, energy expenditure outstrips restorative processes and may be confined to a single organ. 2. Sensation of boredom and lassitude due to absence of stimulation, monotony, or lack of interest in one's surroundings.

auditory f., temporary shift of threshold sensitivity following exposure to sound.

battle f., shell shock; a term used to denote psychiatric illness consequent to the stresses of battle. See also war neurosis.

functional vocal f., phonasthenia.

fat-pad. An accumulation of somewhat encapsulated adipose tissue.

Bichat's f.p., *corpus adiposum buccae*.

Imlach's f.p., fat surrounding the round ligament of the uterus in the inguinal canal.

fatty (fat'ē). Oily or greasy; relating in any sense to fat.

fatty acid. Any acid derived from fats by hydrolysis (e.g., oleic, palmitic, or stearic acids); any long-chain monobasic organic acid.

diethenoid f. a., a f. a. containing two double bonds, e.g., linoleic acid.

saturated f. a., a f. a., the carbon chain of which contains no ethylenic or other unsaturated linkages between carbon atoms (e.g., stearic acid and palmitic acid); called saturated because it is incapable of absorbing any more hydrogen.

f. a. thiokinase, (1) long chain: long-chain fatty acid-CoA ligase; (2) medium chain: butyrate-CoA ligase.

unsaturated f. a., a f. a., the carbon chain of which possesses one or more double or triple bonds (e.g., oleic acid, with one double bond in the molecule, and linoleic acid, with two); called unsaturated because it is capable of absorbing additional hydrogen.

fauces, gen. faucium (faw'sēz, faw'sē-üm) [L. the throat] [NA].

The space between the cavity of the mouth and the pharynx.

faucial (faw'shāl). Relating to the fauces.

faucitis (faw-si'tis). Inflammation of the fauces.

fauna (faw'nă) [Mod. L. application of *Fauna*, sister of *Faunus*, a rural deity]. The animal forms of a continent, district, locality, or habitat.

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